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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,192	06/06/2002	Brigitte Desiree Alberte Colau	B45194	8137
20462	7590	06/28/2005		
SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939			EXAMINER WANG, LOUISE Z	
			ART UNIT 1648	PAPER NUMBER

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/049,192	Applicant(s) COLAU ET AL.	
	Examiner Louise Wang	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 40-78 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's Preliminary Amendment, filed February 6, 2002, is acknowledged.

Claims 1-39 have been canceled.

Claims 40-78 have been added.

Claims 40-78 are pending.

It is noted that Claim 49 makes reference to figures. The claims, when possible, should stand their own. Applicant is urged to amend the claims to recite specific SEQ ID Nos.

Sequence Compliance

The specification and claims are objected to for failing to adhere to the requirements of the sequence rules. Applicant must append SEQ ID Nos. to all mentions of specific sequences in the claims and the specification, including, the figures. See 37 CFR §1.821(d). Full compliance is required in response to this Restriction Requirement. A reply that fails to comply will be considered to be non-responsive and may result in abandonment of this application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 40-52, drawn to an attenuated human rotavirus population comprising at least one of the rotavirus proteins.

Group II, claims 53-56, drawn to a method of production of an attenuated human rotavirus population.

Group III, claims 57-76, drawn to a vaccine composition comprising a live attenuated human rotavirus and an antacid.

Group IV, claim 77, drawn to a method of manufacture of a rotavirus vaccine comprising admixing a lyophilized live attenuated human rotavirus with an antacid and a viscous agent.

Group V, claim 78, drawn to a method of preventing rotavirus infection in humans by administering to a human subject in need thereof an effective amount of a vaccine.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature among these inventions is an attenuated rotavirus comprising an antigen from a human rotavirus. However, it is not an improvement over the prior art of Clark *et al.* (US Patent No. 5,626,851).

Clark *et al.* teach novel rotavirus reassortants that contain the gene encoding the VP4 or VP7 neutralization antigen of a human rotavirus, vaccines employing the novel reassortants, and methods of preparation and administration (see entire document, e.g., column 21, lines 15-24, and 41-47).

Since Applicant's claims do not make a contribution over the prior art, they do not relate to a single general inventive concept and, thus, lack unity of invention.

Species Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If Group I is elected, applicant is required to elect a species wherein the viral protein is:

- (a) VP4;
- (b) VP7; or
- (c) VP4 and VP7.

Applicant is further required to elect a species wherein VP4 comprises at least:

- (i) an adenine base (A) at position 788;
- (ii) an adenine base (A) at position 802;
- (iii) a thymine base (T) at position 501; or
- (iv) an adenine base (A) at positions 788 and 802 and a thymine base (T) at position 501

from the start codon.

Applicant is also required to elect a species wherein VP7 comprises at least:

- (v) a thymine (T) at position 605;
- (vi) an adenine (A) at position 897;
- (vii) a guanine (G) at position 897;
- (viii) a thymine (T) at position 605 and an adenine (A) at position 897; or
- (iv) a thymine (T) at position 605 and a guanine (G) at position 897 from the start codon.

If Group II is elected, applicant is required to elect a species wherein the antacid is:

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- (1) sodium citrate;
- (2) aluminum hydroxide;
- (3) calcium carbonate.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Contact Information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Louise Wang
Patent Examiner
June 21, 2005



JEFFREY STUCKER
PRIMARY EXAMINER